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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,797	05/16/2001	James L. Hartley	0942.285000G	2106
26111	7590	03/25/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/855,797

Applicant(s)

HARTLEY ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 52-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/4/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt is acknowledged of a supplemental amendment, filed 1/5/2004 in response to a Notice of Nonresponsive amendment. In the response filed 1/5/2004 several claims were amended (claims 52-53, 57 & 66). Claims 52-68 are pending in the instant application.

Any rejection of record in the previous office action not addressed herein is withdrawn. This action is not final as some of the grounds for rejection made herein were not necessitated by applicants' amendment of the claims.

### ***Information Disclosure Statement***

Receipt is acknowledged of an electronic information disclosure statement (IDS) and information disclosure statement, filed 11/4/2003. The signed and initialed PTO Forms 1449 have been mailed with the instant action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection.**

Each of the rejected claims recites the limitation "portions thereof" with reference to a first recombination site. It is unclear the minimal part of a recombination site that can be considered as satisfying this limitation. For example, could a single nucleotide present in a

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recombination site (e.g. a restriction endonuclease site or in a LoxP site) be considered as a “portion” of the recombination site in the context of the claims? Or is there some minimal functional requirement that is necessary in order to satisfy the claim limitation of being a “portion” of a recombination site in the rejected claims?

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejected claims are directed to *in vitro* methods for synthesizing one or more nucleic acid molecules comprising one or more recombination sites. The methods comprise 1) obtaining at least one isolated linear nucleic acid molecule, 2) contacting the molecule with one or more adapters comprising a first recombination site or portions thereof under conditions sufficient to add one or more of said adapters to one or more termini of the linear nucleic acid molecule, and 3) mixing the linear nucleic acid molecule with at least one vector *in vitro* in the presence of at least one recombination protein under conditions sufficient to cause recombination of the linear nucleic acid molecule with the vector.

The instant specification defines recombination proteins at page 23, lines 25-27:

“Recombination proteins[:] include excisive or integrative proteins, enzymes, co-factors or associated proteins that are involved in recombination reactions involving one or more recombination sites. See Landy (1994), *infra*.” The specification does not explicitly define the

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term “recombination site”, allowing the skilled artisan to interpret the term broadly to include any site within a nucleic acid that allows it to recombine with a heterologous nucleic acid molecule. The definition provide by the instant specification for the term is at page 29, lines 5-9: “Adapter: is an oligonucleotide or nucleic acid fragment or segment (preferably DNA) which comprises one or more recombination sites (or portions of such recombination sites) which in accordance with the invention can be added to a circular or linear Insert Donor molecule as well as other nucleic acid molecules described herein.” Given a reasonably broad interpretation of the claim limitations, the rejected claims read on any cloning methodology featuring the use of a linear DNA substrate (e.g. a phage genomic DNA) for PCR amplification with primers (i.e. adapters) comprising sequences that can be used to insert the amplified DNA into a vector (e.g. restriction enzyme sites) and subsequent insertion of the amplified insert DNA into a recombination vector.

Claims 52-53, 55, 57-61, 66-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Bebee et al (U.S. Patent No. 5,434,066; of record; see the entire patent). **This is a new grounds of rejection.**

Bebee et al teach the generation of several different vectors where desired sequences were obtained from the phage P1 genome (e.g. P1 vir phage used as a source of genomic DNA) via PCR amplification (Examples 1-2, columns 11-12). For example, the incA region of P1 was amplified from phage P1 vir genomic DNA and subsequent insertion into the BspHI site of vector pSPORT1 (Example 3).

***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

  
GERRY LEFFERS  
PRIMARY EXAMINER